

REMARKS

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the amendments, remarks, and enclosures herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1, 5-6, 19-24, 26-30, 32-36 and 41-45 are now pending in this application.

Claims 1, 19 and 22 have been amended, claims 10-18, 25 and 31 have been canceled, and new claims 44 and 45 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE OBJECTIONS TO THE DECLARATION ARE OVERCOME

The Office Action objected to the declaration as failing to contain the city and state or foreign country of residence of each inventor. Submitted herewith is an application data sheet which provides such information. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claims 1, 5, 6, 10-20, 22, 23 and 25-32 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not sufficiently described to reasonably convey that applicants were in possession of the invention at the time of filing. Claims 1, 5, 6 and 10-32 were also rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejections are respectfully traversed and will be addressed in turn.

Claim 1 has been amended herein to claim only those compounds having a steroidal ring system with a sulphamate group in the 3 position and an (oxy)hydrocarbyl group in the 2

position. Compounds such as MeOEMATE, 2-EtEMATE and 2-MebisEMATE are within the scope of amended claim 1. The Office Action recognized that these specific compounds were disclosed in the specification as having the disclosed activities. Accordingly, the amendment of claim 1 overcomes the Office Action's presumption that Applicants allegedly were not in possession of the claimed invention as the Office Action has admitted that Applicants were in possession of the invention at least to the extent that MeOEMATE, 2-EtEMATE and 2-MebisEMATE are claimed. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully submitted.

Turning now to the enablement rejection, Applicants note that the compound EMATE is no longer within the scope of claim 1.

The Office Action states that the specification is not enabled because while the *in vitro* data therein indicates "that the composition could be used to treat a subject with estrogen dependent breast cancer, which would enable the composition", *in vivo* experiments "demonstrate that treatment with EMATE results in increased levels of estrogen, and so is counter-indicated for treatment." Office Action at 7.

As stated above, the compound EMATE is no longer within the scope of amended claim 1. As explained by the enclosed publication, although EMATE has potent estrogenic properties, 2-substituted analogues were designed to have reduced estrogenic activities. Therefore, one of skill in the art would expect to see increased estrogen levels following treatment with EMATE, in contrast to the results obtained by treatment with 2-substituted analogues. Accordingly, as EMATE is not within the scope of the pending claims, the data relating to EMATE should not be considered to contradict the enabling *in vitro* data presented as to 2-MeOEMATE, 2-EtEMATE and 2-MebisEMATE.

Furthermore, the Examiner is invited to review WO 00/66095, WO 02/16394, and WO 04/085459, all of which are included in the accompanying Information Disclosure Statement. Each of these documents provide further documentation of apoptosis activity as follows: WO 00/66095 demonstrates the apoptosis activity of 2-EtEMATE in example 7 (page 45); WO 02/16394 demonstrates the apoptosis activity of compound 7 in example 5 (page 66); WO 04/085459 demonstrates the apoptosis activity of compounds STX 68, 140, 640 and 641 on page 136. Therefore, one of skill in the art would be aware of the breadth of polycycle-sulphamate

compounds having apoptosis activity, which further demonstrates that the present claims are, in fact, enabled.

Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

IV. INFORMATION DISCLOSURE STATEMENT

The Examiner's attention is respectfully drawn to the document listed on the accompanying PTO Form 1449. A copy of the document is enclosed.

The filing of this Information Disclosure Statement is not an admission that the document identified herein constitutes prior art to the present application. Entry of this Information Disclosure Statement is respectfully solicited, and the Examiner is requested to initial and return a copy of the PTO-1449 to the Applicant. As this Information Disclosure Statement is being filed after the mailing of a first office action on the merits, enclosed is a check in the amount of \$180.00 in payment of the fee therefore. The Commissioner is hereby authorized to charge any other fee occasioned by this paper, or to credit any overpayment in fees, such may be charged or credited to Deposit Account No. 50-0320.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, we respectfully request a personal interview with the Examiner, prior to issuance of any paper other than a Notice of Allowance; and, pursuant to this request the Examiner is also invited to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and enclosures herewith, the application is now in condition for allowance. Consequently, reconsideration and withdrawal of the rejections, and prompt issuance of a notice of allowance, are respectfully requested.

Respectfully submitted,
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